1. IDENTIFICATION

Product identifier

Product code: PR100
Product Name: PREDNISOLONE ACETATE, MICRONIZED, USP

Other means of identification

Synonyms: Pregna-1,4-diene-3,20-dione, 21-(acetyloxy)-11,17-dihydroxy-, (11-beta)- (9CI)
Prednisolone 21-acetate
Meticortelone acetate

CAS #: 52-21-1
RTECS #: TU4152500
Cl#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: Medication.
Uses advised against: No information available

Supplier:
Spectrum Chemical Mfg. Corp
14422 South San Pedro St.
Gardena, CA 90248
(310) 516-8000

Order Online At: https://www.spectrumchemical.com
Emergency telephone number: Chemtrec 1-800-424-9300
Contact Person: Martin LaBenz (West Coast)
Contact Person: Ibad Tirmiz (East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

<table>
<thead>
<tr>
<th>Reproductive toxicity</th>
<th>Category 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific target organ toxicity (repeated exposure)</td>
<td>Category 1</td>
</tr>
</tbody>
</table>

Label elements

Danger

Hazard statements
Suspected of damaging fertility or the unborn child
Causes damage to organs through prolonged or repeated exposure
Hazards not otherwise classified (HNOC)
Not Applicable

Other hazards
Not available

Precautionary Statements - Prevention
Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Wear protective gloves/protective clothing/eye protection/face protection
Do not breathe dust/fume/gas/mist/vapors/spray
Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product

Precautionary Statements - Response
IF exposed or concerned: Get medical advice/attention

Precautionary Statements - Storage
Store locked up

Precautionary Statements - Disposal
Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Weight %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prednisolone Acetate</td>
<td>52-21-1</td>
<td>100</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

First aid measures

General Advice: National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.

Skin Contact: Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops. Consult a physician if necessary.

Eye Contact: Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If eye irritation persists, consult a specialist.

Inhalation: Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Obtain medical attention.

Ingestion: Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician if necessary.

Most important symptoms and effects, both acute and delayed

Symptoms May cause eye/skin/respiratory tract irritation
Glucocorticoids (Corticosteroids): Ingestion may cause osteoporosis and bone fractures,

Product code: PR100       Product name: PREDNISOLONE ACETATE, MICRONIZED, USP
back pain, joint pain/stiffness, numbness, weakness, infection, delayed wound healing, thinning skin, bruising, acne, menstrual irregularities, headache, sweating, eye pain, vision changes, mental and behavior changes, fever, muscle pain, immune system depression, purple lines on skin, tremors, Cushing's syndrome, electrolyte imbalance (sodium and fluid retention, potassium loss (hypokalemia))

Indication of any immediate medical attention and special treatment needed

Notes to Physician: Treat symptomatically.

Protection of first-aiders
First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

5. FIRE-FIGHTING MEASURES

**Extinguishing Media**
Suitable Extinguishing Media: Dry chemical. Carbon dioxide (CO2). Water spray. Foam.

Unsuitable Extinguishing Media:
No information available.

**Specific hazards arising from the chemical**

Hazardous Combustion Products:
Carbon Monoxide, Carbon Dioxide.

Specific hazards:
May be combustible at high temperatures.

**Special Protective Actions for Firefighters**

Specific Methods:
No information available.

Special Protective Equipment for Firefighters:
As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment and emergency procedures**

Personal Precautions:
Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Use personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid contact with skin, eyes and clothing. Avoid breathing dust. Remove all sources of ignition.

Environmental precautions
Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

Methods and material for containment and cleaning up

Methods for containment
Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

Methods for cleaning up
Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

**Precautions for safe handling**

Technical Measures/Precautions:

**Product code:** PR100
**Product name:** PREDNISOLONE ACETATE, MICRONIZED, USP
Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. All equipment used when handling the product must be grounded. Keep away from incompatible materials.

**Safe Handling Advice**
Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Do not ingest. Do not breathe dust. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

**Conditions for safe storage, including any incompatibilities**

**Technical Measures/Storage Conditions:**  
Keep container tightly closed in a dry and well-ventilated place. Store at 25 °C. Excursions between 15°C/59°F and 30°C/86°F that are experienced in pharmacies, hospitals, and warehouses and during shipping are allowed. Store away from incompatible materials.

**Incompatible Materials:**  
Strong oxidizing agents

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Control parameters**

**National occupational exposure limits**

#### United States

<table>
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<tr>
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<th>NIOSH</th>
<th>ACGIH</th>
<th>AIHA WEEL</th>
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#### Canada

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<th>Canada - Ontario</th>
<th>Canada - Quebec</th>
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#### Australia and Mexico

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<th>Mexico</th>
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<td>Prednisolone Acetate</td>
<td>52-21-1</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

**Appropriate engineering controls**

**Engineering measures to reduce exposure:**  
Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

**Individual protection measures, such as personal protective equipment**

**Personal Protective Equipment**

**Eye protection:**  
Goggles or Safety glasses with side-shields.

**Skin and body protection:**  
Long sleeved clothing, apron

**Product code:** PR100  
**Product name:** PREDNISOLONE ACETATE, MICRONIZED, USP
Gloves

**Respiratory protection:** Effective dust mask. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds), inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.

**Hygiene measures:** Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
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<tr>
<th>Property</th>
<th>Value</th>
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<td>Solid</td>
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<tr>
<td><strong>Appearance:</strong></td>
<td>Crystalline powder.</td>
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<tr>
<td><strong>Odor:</strong></td>
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<tr>
<td><strong>Taste:</strong></td>
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<tr>
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<tr>
<td><strong>Boiling point/range(°C/°F):</strong></td>
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<tr>
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<tr>
<td><strong>Appearance:</strong></td>
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</tr>
<tr>
<td><strong>Taste:</strong></td>
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<tr>
<td><strong>Formula:</strong></td>
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<td><strong>Formula:</strong></td>
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<td><strong>Flammability:</strong></td>
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<td><strong>Flashpoint (°C/°F):</strong></td>
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<tr>
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<tr>
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<td>No information available</td>
</tr>
<tr>
<td><strong>Odor threshold (ppm):</strong></td>
<td>No information available</td>
</tr>
<tr>
<td><strong>Miscibility:</strong></td>
<td>No information available</td>
</tr>
</tbody>
</table>

### 10. STABILITY AND REACTIVITY

**Reactivity:** May react with strong oxidizers

**Chemical stability**

**Stability:** Stable under recommended storage conditions.

**Possibility of Hazardous Reactions:** Hazardous polymerization does not occur

**Conditions to avoid:** Heat. Incompatible materials. Avoid dust formation.

**Incompatible Materials:** Strong oxidizing agents

**Hazardous decomposition** Carbon oxides.

**Product code:** PR100

**Product name:** PREDNISONOLONE ACETATE, MICRONIZED, USP
Other Information
Corrosivity: No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:
Inhalation. Ingestion.

Acute Toxicity

Component Information

<table>
<thead>
<tr>
<th>Prednisolone Acetate</th>
<th>CAS-No.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>52-21-1</td>
</tr>
</tbody>
</table>

LD50/oral/rat = No information available
LD50/oral/mouse = No information available
LD50/dermal/rabbit = No information available
LD50/dermal/rat = No information available
LC50/inhalation/rat = No information available
LC50/inhalation/mouse = No information available
Other LD50 or LC50 information = No information available

Product Information

LD50/oral/rat =
VALUE- Acute Tox Oral = No information available

LD50/oral/mouse =
Value - Acute Tox Oral = No information available

LD50/dermal/rabbit
VALUE-Acute Tox Dermal = No information available

LD50/dermal/rat
VALUE -Acute Tox Dermal = No information available

LC50/inhalation/rat
VALUE-Vapor = No information available
VALUE-Gas = No information available
VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse
VALUE-Vapor = No information available
VALUE - Gas = No information available
VALUE - Dust/Mist = No information available

Symptoms

Skin Contact: May cause skin irritation.
Eye Contact: May cause eye irritation.

Inhalation May cause irritation of respiratory tract.

Ingestion Corticosteroids (glucocorticoids): Nausea, vomiting, headache. May cause bone fractures, back pain, joint pain or stiffness, weakness, high blood pressure, increased appetite, infection, delayed wound healing, thinning skin, bruising, purple lines on skin, increased hair growth, acne, redistribution of body fat, menstrual irregularities, impotence, increased sweating, eye pain, vision changes, mental and personality changes, swelling, lightheadedness, numbness, tremors, Fluid and electrolyte imbalance (sodium and fluid retention), suppression of calcium absorption and increased calcium excretion, potassium loss, hypokalemic alkalosis, Cushing's syndrome, immune system depression.

Aspiration hazard No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Chronic Toxicity Prolonged or repeated eye contact with glucocorticoids/corticosteroids may affect vision (glaucoma, cataracts). Prolonged or repeated skin contact with corticosteroids/glucocorticoids may cause dryness, folliculitis, acne, hypopigmentation, dermatitis, thinning of skin (skin atrophy). Prolonged or repeated ingestion of corticosteroids may cause osteoporosis and bone fractures due to mobilization of calcium (reduced calcium absorption) and phosphorus, hypokalemia due to increase urinary loss of potassium, development of glaucoma and cataracts, muscle weakness/muscle wasting, swelling of the feet or lower legs due fluid and sodium retention, hip or shoulder pain, irregular heartbeat. It may affect the liver, kidneys, pancreas (pancreatitis), blood (changes in serum composition), behavior/central nervous system (anxiety, nervousness or restlessness, trouble sleeping, mental disturbances such as psychosis, euphoria, depression), protein metabolism, lipid metabolism, carbohydrate metabolism causing insulin resistance, hyperglycemia, diabetes, and the immune system (immunosuppressant) causing increased susceptibility to infections, thinning skin. Repeated ingestion of large doses of corticosteroids may also produce other symptoms typical of hyperactivity of the adrenal gland and overproduction of cortisol (Cushing's Syndrome) such moon-face, buffalo hump, increased bruising, ecchymoses, striae, and acne, menstrual irregularities, amenorrhea, sometimes hirsutism (deepening of the voice in women), and excess hair growth (in women). Corticosteroids may also have an inhibitory effect on wound healing. This may affect persons who have experienced recent nasal ulcers, nasal surgery or nasal trauma.

Sensitization: No information available.

Mutagenic Effects: No information available

Carcinogenic effects: Not considered carcinogenic.

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>IARC</th>
<th>ACGIH - Carcinogens</th>
<th>NTP</th>
<th>OSHA HCS - Carcinogens</th>
<th>Australia - Notifiable Carcinogenic Substances</th>
<th>Australia - Prohibited Carcinogenic Substances</th>
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<tr>
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<td>Not listed</td>
<td>Not listed</td>
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</tr>
</tbody>
</table>

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

Group 3 - Not classifiable as to its carcinogenicity to humans

NTP (National Toxicology Program)

Product code: PR100  Product name: PREDNISOLONE ACETATE, MICRONIZED, USP
Reproductive toxicity  
Suspected of damaging fertility or the unborn child

Reproductive Effects:  
No information available

Developmental Effects:  
May cause adverse developmental effects based on animal data
Possible risk of harm to the unborn child
Prednisone can be associated with fetal growth impairment in humans
Glucocorticoid medication used during pregnancy has been associated with an increased risk of cleft palate and impaired fetal growth by some studies (REPROTOX)

Teratogenic Effects:  
No information available

Specific Target Organ Toxicity

STOT - single exposure  
No information available.

STOT - repeated exposure  
No information available.

Target Organs:  
No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects:  
No data available.

Persistence and degradability:  
No information available

Bioaccumulative potential:  
No information available.

Mobility:  
No information available.

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:
Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:
Empty containers should be taken for local recycling, recovery or waste disposal

<table>
<thead>
<tr>
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<th></th>
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<td>52-21-1</td>
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<td>None</td>
<td>None</td>
<td>None</td>
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</table>

14. TRANSPORT INFORMATION

DOT

UN-No:  
Not Regulated

Proper Shipping Name:  
No information available

Hazard Class:  
No information available

Subsidiary Class  
No information available

Packing group:  
No information available

Emergency Response Guide Number  
No information available

Product code:  PR100
Product name:  PREDNISOLONE ACETATE, MICRONIZED, USP
Marine Pollutant: No data available
DOT RQ (lbs): No information available
Special Provisions: No Information available
Symbol(s): No information available
Description: No information available

**TDG (Canada)**
UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Marine Pollutant: No Information available
Description: No information available

**ADR**
UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available

**IMO / IMDG**
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Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Marine Pollutant: No Information available

**RID**
UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available

**ICAO**
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Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available

**IATA**
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Subsidiary Risk: No information available
Packing Group: No information available
ERG Code: No information available
Special Provisions: No information available

### INTERNATIONAL INVENTORIES

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<th>Japan ENCS</th>
<th>CHINA</th>
<th>Australia</th>
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<td>Product name: PREDNISOLONE</td>
<td>ACETATE, MICRONIZED, USP</td>
<td>9 / 11</td>
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</table>
### U.S. Regulations

**California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.**

**Chemicals Known to the State of California to Cause Cancer:**
This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

**Chemicals Known to the State of California to Cause Reproductive Toxicity:**
WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm (See table below)

#### Components

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Carcinogen</th>
<th>Developmental Toxicity</th>
<th>Male Reproductive Toxicity</th>
<th>Female Reproductive Toxicity:</th>
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#### CERCLA/SARA

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<th>Section 302 Extremely Hazardous Substances and TPQs</th>
<th>Section 302 Extremely Hazardous Substances and RQs</th>
<th>Section 313 - Chemical Category</th>
<th>Section 313 - Reporting de minimis</th>
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#### U.S. TSCA

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<th>TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)</th>
<th>TSCA 8(d) - Health and Safety Reporting</th>
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#### Canada

**WHIMIS 2015 - GHS Classifications**

WHIMIS 2015 Hazard Classification

Information: The WHIMIS 2015 classification of this product has not been validated or reviewed yet.

**Canada Hazardous Products Regulation**

This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

#### Inventory

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<td>Prednisolone Acetate</td>
<td>52-21-1</td>
<td>Not listed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prednisolone Acetate</td>
<td>52-21-1</td>
<td>Not listed</td>
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</table>

**EU Classification**

**Product code:** PR100  
**Product name:** PREDNISOLONE ACETATE, MICRONIZED, USP
EU GHS - SV - CLP 1272/2008

Components | CAS-No. | EU GHS - SV - CLP (1272/2008)
--- | --- | ---
Prednisolone Acetate | 52-21-1 | 

EU - CLP (1272/2008)

R-phrase(s)
R22 - Harmful if swallowed.
R63 - Possible risk of harm to the unborn child.

S-phrase(s)
S46 - If swallowed, seek medical advice immediately and show this container or label.
S36/37 - Wear suitable protective clothing and gloves.

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration Limits:</th>
<th>Safety Phrases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prednisolone Acetate</td>
<td>52-21-1</td>
<td>No information</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:
Xn - Harmful.

16. OTHER INFORMATION

Preparation Date: 10/30/2018
Revision Date: 10/30/2018
Prepared by: Sonia Owen

Disclaimer:
All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet

Product code: PR100
Product name: PREDNISOLONE ACETATE, MICRONIZED, USP